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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,041	02/04/2002	Ni Ding	10177-110-999	6071
20583	7590	03/10/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,041	DING ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2004 has been entered.

Drawings

The drawings were received on December 23, 2004. These drawings are approved. However, it is noted that the quality of the drawings is about the same as the previous drawings. The poor quality is most likely due to the nature of scanning such photographs into an image file. The result of such scanning is a silhouette of the structure where no structure of the facing surface can be seen. Since this is the best that can be done, it is accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 24-38, the range of "about 4-6 μm " or "about 4 μm " renders the claim scope indefinite because the specification fails to provide some

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standard for measuring that degree to which “about” modifies claim scope. Therefore, one of ordinary skill would not know how broadly to interpret “about” as to what would fall within the claim scope and what would not. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples. (emphasis added here)

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes “about 4-6 μm ” and what does not. This is a critical and defining limitation of the claim, particularly because the prior art discloses an overlapping range of 0.1 to 3 μm . It must be clear as to what falls within the claims’ scopes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24-33 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (US 5,716,918) alone. Hunter meets the claim language where the coating can contain the same polymer as claimed (see column 3, lines 39-61), the stent can have openings between braids or in the end openings (see column 22, lines 29-31), the biologically active material is included in the coating (see column 3, line 39 to column 4, line 41), the particles can overlap or be close to the same range in that the range of 0.1 to 3 μm is disclosed (see column 17, lines 27-40), and the coating conforms to the stent such that it does not change the contour thereof (see column 22, lines 58-64). However, Hunter fails to disclose an average particle size that falls within the claimed range. Nonetheless, the Examiner asserts that the claimed range is *prima facie* obvious in view of Hunter because no criticality for the claimed range has been shown; see MPEP 2144.05, which is incorporated herein by reference. Rather, the claimed range is merely a preferred range within the range of less than 15 microns; see page 21, lines 13-22.

With regard to claim 26, the 20% concentration of Hunter is considered to be within the claimed range of about 25-45% as claimed; see column 53, lines 20-38.

With regard to claim 27, Applicant is directed to column 16, line 5.

Claims 34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (US 5,716,981) in view of Dinh et al (US 5,591,227). Hunter fails to disclose the use of silicone and heparin in the coating as claimed. However, Dinh teaches that it was known to use silicone and heparin in similar coatings within the art; see column 2, lines 36-56, column 5, lines 44-55 and column 7, lines 7-52. Therefore, it

is the Examiner's position that it would have been *prima facie* obvious to include heparin and silicone in the coating of Hunter in order to improve the anticoagulant and elasticity properties of the coating.

Response to Arguments

Applicant's arguments filed December 23, 2004 have been fully considered but they are not persuasive.

In response to the Section 112 rejection traversal that there is guidance for the 4 to 6 micron range on page 20, lines 24-27 of the specification, the Examiner disagrees and notes that there is no discussion of the meaning of "about" in this excerpt. Since the prior art discloses such a close embodiment, the meaning and scope of "about" must be clearly discernable. For this reason, the rejection has not been withdrawn.

In response to the Section 103 rejection traversal with Hunter alone, it appears that Applicants' argument hinges on the belief that the drug itself must be a particle. However, the Examiner thought that it was apparent that the microspheres were the claimed particles. Since the microspheres contain the drug, the claim language is fully met. It would be improper for the Examiner to interpret the claim language more narrowly.

Since the other rejection is based upon this understanding, the Examiner asserts that it is also tenable.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
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